DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Faulding Pharmaceutical Co.
Attention: Kala Patel
11 Commerce Drive
Cranford, NJ 07016

Docket No. 99P-2252/CP1

Dear Dr. Patel:

This letter regards your petition filed on July 8, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL, and 9 mg/mL, 10 mL vials. The listed drug products to which you refer in your petition are Aredia® (Pamidronate Disodium) for Injection, 30 mg/vial, 60 mg/vial and 90 mg/vial manufactured by Novartis.

Your petition cannot be evaluated. You are subject to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published, December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632), but we need additional information to determine whether pediatric studies are necessary in children with Paget's disease, and in hypercalcemia of malignancy in the pediatric population. Please submit information to your petition in order for the agency to determine whether you are eligible for a waiver.

Waivers are granted if: (1) The product (a) did not represent a meaningful therapeutic benefit over existing treatments, and (b) was not likely to be used in a substantial number of pediatric patients as a whole, or was not likely to be used in a substantial number of one or more pediatric subpopulations, or (2) necessary studies were impossible or highly impractical, because, for example, the number of such patients was so small or geographically dispersed, or (3) there were evidence strongly suggesting that the product would be ineffective or unsafe in some or all pediatric populations.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, and 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

99P-2252

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